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| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | ATTORNEY'S DOCKET NUMBER 4258-112 U.S. APPLICATION NO. (If known, see 37 CFR 1.5) Not Yet Assigned 10/540212 |
| INTERNATIONAL APPLICATION NO. PCT/ES03/000635 | INTERNATIONAL FILING DATE 16 December 2003 | PRIORITY DATE CLAIMED 18 December 2002 |
| TITLE OF INVENTION: METHOD OF DIAGNOSING NON-ALCOHOLIC STEATOHEPATITIS (NASH) USING MOLECULAR MARKERS | | |
| APPLICANT(S) FOR DO/EO/US: Jose Maria Mato De La Paz, Fernando Corrales Izquierdo, Enrique Santamaria Martinez | | |

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

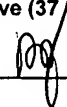
1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)), published as International Publication No. WO 04/05520.
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (unsigned)
10. ☒ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Credit Card Authorization Form

This collection of information is required by 37 CFR 1.414 and 1.491–1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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| U.S. APPLICATION NO. (if known, see 37 CFR 1.5) Not Yet Assigned 10/540212 | | INTERNATIONAL APPLICATION NO. PCT/ES03/00635 | | ATTORNEY'S DOCKET NUMBER 4258-112 | |
| The following fees are submitted: | | | | | |
| 21. | <input checked="" type="checkbox"/> | Basic national fee..... | | \$300.00 | \$ 300.00 |
| 22. | <input checked="" type="checkbox"/> | Examination fee | | | |
| If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... | | | | \$100.00 | \$ 200.00 |
| All other situations..... | | | | \$200.00 | |
| 23. | <input checked="" type="checkbox"/> | Search fee | | | |
| Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... | | | | \$100.00 | \$ 500.00 |
| International Search Report prepared and provided to the Office..... | | | | \$400.00 | |
| All other situations..... | | | | \$500.00 | |
| TOTAL OF 21, 22 and 23 = | | | | | \$1,000.00 |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$40 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | | RATE | |
| 31 | -100 = 0 | /50 = 0 | | x \$250.00 | \$ 0.00 |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)). | | | | | \$ 0.00 |
| CLAIMS | | NUMBER FILED | NUMBER EXTRA | RATE | \$ |
| Total claims | | 16- 20 = | 0 | X \$50.00 | \$ 0.00 |
| Independent claims | | 3- 3 = | 0 | X \$200.00 | \$ 0.00 |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | | + \$360.00 | \$ 0.00 |
| TOTAL OF ABOVE CALCULATIONS = | | | | | \$1,000.00 |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2. | | | | | \$1,000.00 |
| SUBTOTAL = | | | | | \$1,000.00 |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)). | | | | | \$ 0.00 |
| TOTAL NATIONAL FEE = | | | | | \$ 0.00 |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | | | | \$ 0.00 |
| TOTAL FEES ENCLOSED = | | | | | \$ 1,000.00 |
| a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>08-3284</u> . A duplicate copy of this sheet is enclosed. d. <input checked="" type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. | | | | | |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. | | | | | |
| SEND ALL CORRESPONDENCE TO: INTELLECTUAL PROPERTY/TECHNOLOGY LAW P.O. BOX 14329 Research Triangle Park, North Carolina 27709 | | | | SIGNATURE:  Steven J. Hultquist NAME 28,021 REGISTRATION NUMBER | |


TRADEMARK OFFICE
JC17 Rec'd PCT/PTO 15 JUN 2005

Submitted herewith for filing under the provisions of 37 CFR §1.53 and 35 U.S.C. §371 is the above-referenced patent application, based on International Patent Application No. PCT/ES03/000635 and

claiming priority of Spanish Patent Application No. P200202911. A copy of International Published Application No. WO 2004/000635 is included. Also included is an unsigned Declaration and Power of Attorney¹, and a Credit Card Authorization Form authorizing the \$1000.00 filing fee, and 35 U.S.C. §371 transmittal forms.

Please direct correspondence relating to this application to Steven J. Hultquist, Intellectual Property Technology Law, P.O. Box 14329, Research Triangle Park, NC 27709, and direct telephonic communications relating to this application to Steven J. Hultquist at (919) 419-9350.

Respectfully submitted,



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Attorney for Applicants

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Attorney Ref.: 4258-112**

¹ A fully executed Declaration and Power of Attorney will be submitted in due course, following notification of the application number for the application.